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BIOMET

510(k) Summary

APR - 3 2007

Preparation Date: January 24, 2007

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Susan Alexander

Proprietary Name: Echo™ Bi-Metric® Press-Fit Stems

Common Name: Hip Stem

Classification Code(s)/Name(s):

LZO – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR §888.3353)
KWA – Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (21 CFR §888.3330)
KWZ – Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR §888.3310)
JDL – Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis (21 CFR §888.3320)
JDI – Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR §888.3350)
MAY - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR §888.3353)
MEH – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR §888.3353)
LPH – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR §888.3358)
KWL – Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR §888.3360)
LWJ – Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR §888.3360)
KWY – Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR §888.3390)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Altra Press-Fit Hip Stem K063002 Biomet Manufacturing Corp.

Device Description: The Echo™ Bi-Metric® Press-Fit Stems are hip stems made from Ti-6Al-4V conforming to ASTM F-136. Portions of the devices are coated with Porous Plasma Spray conforming to ASTM F-1580.

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Indications for Use:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2. Rheumatoid arthritis
3. Correction of functional deformity
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
5. Revision of previously failed total hip arthroplasty.

The Echo™ Bi-Metric® Press-Fit Stems are intended for uncemented use only.

Summary of Technologies: The Echo™ Bi-Metric® Press-Fit Stems incorporate a similar design with similar technological features as the predicate hip stems. They have the same intended use, indications for use, and utilize the same Biomet Type I Taper as the predicate stems. These similarities demonstrate that the Echo™ Bi-Metric® Press-Fit Stems are substantially equivalent to the predicate hip stems.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the devices were functional within their intended use.

Clinical Testing: Clinical testing was not required for the predicate devices. Therefore, this submission contains no clinical testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Manufacturing Corp.
% Ms. Susan Alexander
Regulatory Specialist
Post Office Box 587
Warsaw, Indiana 46581

APR - 3 2007

Re: K070274
Trade/Device Name: Echo™ Bi-Metric® Press Fit Stems
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with uncemented acetabular component, prosthesis
Regulatory Class: III
Product Code: KWA
Dated: March 14, 2007
Received: March 15, 2007

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Buch MD for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: Echo™ Bi-Metric® Press Fit Stems

Indications For Use:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2. Rheumatoid arthritis
3. Correction of functional deformity
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
5. Revision of previously failed total hip arthroplasty.

The Echo™ Bi-Metric® Press-Fit Stems are intended for uncemented use only.

Prescription Use YES AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buch MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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